K072040

AUG 23 2007

SPECIAL 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

Trade Name	C-JAWS Cervical Compressive Mini Frame
Common Name	Anterior Cervical Buttress Staple System
Classification Name	Spinal intervertebral body fixation orthosis
Class	II
Product Code	KWQ
CFR section	888.3060
Device panel	Orthopedic
Legally marketed predicate devices	C-JAWS CERVICAL COMPRESSIVE MINI FRAME (K062181)
Submitter	MEDICREA™ TECHNOLOGIES ZI Chef de Baie 17000 La Rochelle France
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 Phone 512-388-0199 email : ortho.medix@sbcglobal.net

2. PREDICATE DEVICE DESCRIPTION

The C-JAWS implant is a single component system of anterior cervical anchoring. The staple is uniquely shaped to conform to the anatomy of the anterior spine. It features two notched arms, which engage the vertebral bodies and works by plastic deformation of the implant's body. The staples are available in multiple sizes the C-JAWS implant is manufactured from CP titanium and has a smooth anodized finish.

3. DESCRIPTION OF DEVICE MODIFICATION

The purpose of this submission is to add additional sizes to the C-JAWS implant range: height of 12.5, 17.5 and 22.5mm and arm lengths of 10, 12, 14 and 17mm.

In addition, radii (R=0.2mm) have been added to the extremity of both legs to reduce the sharpness of the tips of the C-JAWS legs. The modification is effective on the new submitted C-JAWS implants and has been applied to the K062181 cleared implants.

Additional instruments are also added.

4. INTENDED USE

The C-JAWS implant, in conjunction with traditional rigid fixation, is intended for use in cervical fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

5. PERFORMANCE DATA

Biomechanical testing, including pull out fixation tests were conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2007

Medicrea Technologies
% The OrthoMedix Group
Mr. J.D. Webb
1001 Oakwood Blvd.
Round Rock, Texas 78681

Re: K072040
Trade/Device Name: C-JAWS Cervical Compression Mini Frame
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: July 16, 2007
Received: July 25, 2007

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072040

Device Name: C-JAWS Cervical compressive mini frame

Indications for Use

The C-JAWS Cervical Compressive Mini Frame, in conjunction with traditional rigid fixation, is intended for use in cervical fusion procedures as a means to maintain the relative position of weak bony tissue such as allograft or auto grafts. This device is not intended for load bearing applications.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucher for MJM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072040